METHODS AND APPARATUS FOR USE IN CONTACT LENS MANUFACTURE AND PACKAGING

The invention relates to a method of manufacture and packaging of contact lenses, and associated apparatus, in particular of "soft", daily-disposable contact lenses.

Soft contact lenses are now provided in a plastic 'blister' pack containing individual compartments, each of which contains a contact lens and saline fluid and is sealed with a vapour-barrier foil. There are number of variants of 'blister' packs currently available, in a variety of designs. The industry is seeking to manufacture these packs and associated contact lenses as efficiently as possible, and recycling as much material as possible. Several problems prevail that need addressing, and which are described in detail in the following text.

Contact lenses and other types of lenses (e.g. Intraocular lenses) are produced in very high volumes by casting methods, such as Spin Casting and Mould Casting. Both methods involve dispensing a small amount of liquid hydrogel monomer into specially made 'concave' optical moulds. This mould surface forms the front surface of the lens.

In the case of spin casting; the lens is formed by the controlled rotation of a concave optical mould. Spinning causes the liquid monomer to flow evenly up all sides of the concave mould, coating the entire surface. During this time the lens monomer is cured (polymerised) using heat or light to form a hard lens. At the end of the process the lens remain in close contact with the concave surface of the mould, from which it has then to be removed without damage.

In the case of cast moulding; the back surface of the lens is formed by inserting a convex mould into the liquid monomer (which is already held in a mating concave mould) thereby displacing the monomer to form a lens envelope between the specially shaped concave and convex moulds. The liquid monomer is cured as before, by the application of heat or light. At the end of this process the hard lens remains 'sandwiched' between the optical surfaces of the concave and convex mould pieces.

Once the mould-pair is separated the dry, hard, lens generally remains inside the concave mould. Some method is then required for removing the dry lens from the concave mould-piece, to which the curing process has quite intimately attached the lens. There is also a ring of excess material known as “flash” which may need separating also.

One known method of dry lens removal is to slightly deform the mould piece, for example by tapping or pressing on the back of the mould with the opening facing downwards. This will generally break the bond between the mould-piece and the dry lens; however, the dry lens will not fall free of the mould. This can be due to the effects of static electricity or natural adhesion (there being no natural air film between the surface of the lens and the mating surface of the mould-piece, even although there is no actual bonding). Very severe deformation of the mould (for example, by the application of a static load or by heavy hitting) may dislodge the lens, but this can damage the surface or edge of the dry lens. Lenses released in this way frequently suffer unacceptable edge damage. Yield (good lenses as a percentage of total) can be as low as 50% and inspection of all lenses (to segregate the undamaged ones) is required. It is also essential that any fragments of damaged lenses are immediately removed from any surrounding work surfaces or production equipment, because such fragments can become attach to adjacent ‘good’ lenses, thereby creating secondary damage/rejection. Low yield, high inspection and the need for careful segregation results in prohibitive costs for disposable lens manufacture. Also, the resulting unpredictable deformation of the mould has the effect of irrevocably distorting the mould, thereby rendering it unsuitable for repeated moulding operations.

Another, less traumatic method known for separating the lens from the mould is to immerse the mould and lens ‘assembly’ in water. (Before conducting this operation it is, however, first necessary to perform the additional step of removing any flash-ring which surrounds the edge of the lens, if required). The water in which the dry lens is immersed hydrates the lens, expanding it by as much as 50% (depending on the monomer mix being used) and causing it to gently ‘sink’ away from the mould. This

method has the advantage of being non-traumatic for the lens and as a result lens damage is greatly reduced or eliminated. The disadvantage with this method is that the moulding becomes wet and, if the lens is being transferred during the hydration process to some form of blister-pack, then this too becomes wet. Stacking the lenses in suitable hydration tanks, immersing in water and subsequent drying the pack-piece (necessary to effect the successful, leak free, application of a closure foil) all involves relatively high cost. Such wetting and drying processes, even though overcoming the aforementioned problem of distortion of the mould, still renders the moulds unsuitable for repeated cast moulding operations. Finally, it is much harder to transfer hydrated lenses than dry ones, as the hydrated lenses are considerably softer and consequently more prone to damage.

Attempts to transfer lenses in their dry state from a mould to a receptacle in mass-production have been frustrated by static electricity, which causes the lenses to jump and adhere almost randomly to different parts of the apparatus, often depending on the weather.

Accordingly, it is an object of the present invention to provide method and apparatus for mass-production of flexible contact lenses and their packaging that addresses one or more of the aforementioned disadvantages.

According to a first aspect of the present invention, there is provided a method of depositing a dry, un-hydrated contact lens from a carrying head into a receptacle in mass-production, the method comprising pre-dosing said receptacle with a relatively small amount of fluid sufficient to form a small spot in the base of the receptacle, so that when the lens is brought into contact with the fluid the contact of fluid between lens and receptacle captures the lens consistently in the base of the receptacle.

This method greatly improves the reliability of dry lens transfer to a level where it can be used in mass production. Without limiting the scope of the invention to any particular mechanism, it is believed that the fluid provides a holding force to release the contact lens from the head when the head is withdrawn, overcoming any adhesion or

electrostatic attraction that may exist between the lens and the head. The mild anchoring is achieved by the surface tension of the fluid being a stronger force than any force still holding the lens to the manipulator head.

The fluid is preferably pure water, avoiding additives that would reduce surface tension.

The amount of fluid used in the pre-dosing step is a fraction of that used with bulk hydration methods for contact lens manufacture.

A spot of fluid is sufficient to capture the lenses: far less than the quantity required to hydrate the lens. The fluid will be absorbed quickly into the lens material, which is strongly hydrophilic. Consistency of 1 in 500 might be acceptable but 1 in 1000 or better is achievable in practice.

In particular embodiments, the volume of fluid in said spot is less than, say 0.1ml, preferably less than 0.07ml. The average volume may for example be in the range 0.001 ml to 0.07 ml or 0.03 ml to 0.07 ml.

The method may further include adding further fluid after depositing the lenses in order to hydrate the lens.

The method may yet further comprise a washing step wherein fluid surrounding the lens in the receptacle is replaced one or more times after hydration is complete.

The receptacle may in particular constitute part of a package, such as a blister pack, the method further comprising adding a closure to the receptacle at a time after depositing the lens, to form a sealed lens package.

The closure may comprise a foil heat-sealed to the receptacle.

The method may further comprise adding a packing fluid for the lens, while it remains in said receptacle, and prior to adding said closure. The packing fluid may have a different composition to the hydrating fluid, and may have added components for safety and comfort.

The receptacle may be one of a plurality of receptacles, all being pre-dosed with fluid and loaded with lenses simultaneously. In this form the invention enables mass production on a commercial scale.

According to a second aspect of the present invention, there is provided a method of removing a dry, un-hydrated flexible contact lens from a mould comprising:

- providing a lens mould piece, having a concave optical surface and a convex backside surrounded by a flange, said mould being suitably flexible to allow said mould piece portion to deform upon the application of an externally applied force;
- forming and curing a dry contact lens onto the concave optical surface of said mould piece;
- while holding the mould lens-uppermost, applying a downward force to the flange portion of the first piece, applying an upward force to the convex backside to deform said mould piece, said deformation substantially breaking adhesion between the dry contact lens and the concave optical surface of the mould piece; and
- while said forces are applied, capturing and removing the lens from said first optical surface by a lifting probe.

The risk of producing damaged lenses is significantly reduced by using this process. The flexibility of the mould within its elastic limits provides clearance for lifting the lens free of the mould. Furthermore, the elasticity and controlled deformation of the mould allows it to 'relax' back to its original form, if desired. This would allow it to be reused, resulting in significant cost savings. It is noted that moulds have been deformed manually to extract lenses, but this is in a downward orientation for expecting

the lens in a loose, uncontrolled state, and also involves unknown damage to the mould, excluding the possibility of reuse.

The probe may conveniently be a suction probe having a soft tip so as not to damage the lens. Other forms of adhesion, for example by moisture and controlled electrostatic attraction, may be envisaged for the probe.

The method is equally applicable to the manufacture of contact lenses using spin casting or cast moulding, where the contact lens is formed and cured between the concave mould piece and a convex mould piece having a second optical surface, the portions being separated after curing to leave a dry contact lens adhering to the concave optical surface of the first portion.

For applications involving the mould casting of lenses between a first mould piece having a concave optical surface and a second mould piece having a convex optical surface, the method may further include, after the lens has been formed and cured and before the mould pieces have been separated, the step of applying a radial "breaking" force to the outer surface of said first mould piece, said "breaking" force deforming the first mould piece in the region of the junction between said first and second mould pieces, said deformation relative to the rigidity of the hard material which forms a lens and a flash ring causing said hard material to break adhesion with one of said surfaces.

The downward and upward forces and/or "breaking" force may be applied by respective parts of apparatus, arranged to move relative to one another, the apparatus further comprising means to support the mould piece at a defined position between said parts.

It does not matter which part moves or remains stationary, provided there is controlled relative movement. In a practical embodiment, the apparatus is powered by (for example pneumatic) actuators moving opposing jaws to apply the "breaking" force, and moving plungers up from below while the flange is held stationary, to apply the

downward and upward forces. The soft-tipped suction probe then descends to an appropriate depth into the mould piece, to retrieve the lens.

The downward force may be applied by a ring, held against the flange, the ring being formed by a solid surface or multiple lobes applied at intervals around said flange, the suction probe accessing the lens thorough the centre of the ring. The lobes provide for a slight lack of parallelism between the surfaces applying the downward force and the mould. A suitably positioned downward force can ensure that the applied upward force moves the contact lens to a repeatable target location for pick-and-place equipment to collect the lens from, without which the pick-and-place equipment may occasionally miss some of the lenses.

The lens mould piece and force-applying parts may be provided as an array of identical parts, processed simultaneously.

The step of removing the lens from the first optical surface may include removing the lens through a flash ring of excess lens material attached to said mould piece. The lens can be passed through the ring without damage while the mould is being deformed, the deformation very slightly increasing the circumference of the flash ring, and through which an un-deformed lens may then pass.

The method may further comprise depositing the lens from said suction probe into a pre-dosed receptacle, in accordance with the first aspect of the invention as set forth above.

According to a third aspect of the present invention, there is provided a method of processing a contact lens in a packaging receptacle, comprising:

- providing a packaging receptacle comprising a concave cavity;
- transferring into said receptacle an unhydrated contact lens;
- providing a finishing head comprising adjacent inlet and outlet nozzles, said inlet nozzle tapered so that a focussed stream of fluid can be directed onto and behind the contact lens from a point off the axis of the cavity, said outlet nozzle located

such that at a time after the inlet fluid has been added to the receptacle the fluid can be extracted from a point on or near the axis of the cavity;

- hydrating said lens in the concave cavity of the receptacle with a hydrating fluid, and at a time after said lens has been hydrated, extracting said hydrating fluid;
- washing the hydrated lens in said concave cavity with a flushing fluid applied by said inlet nozzle, and at a time after said lens has been washed, extracting said flushing fluid by said outlet nozzle.

The method may further comprise the steps of:

- repeating the washing step a sufficient number of times to suitably diminish the level of contaminants;
- filling the majority of the volume of said receptacle with a packing fluid; and
- hermetically sealing a closure to said receptacle to form a packaged, sealed and hydrated contact lens.

The same or different nozzles may be used for the hydration fluid and the packing fluid. Given that hydration takes time, however, the hydration step can be initiated at a separate workstation using a different nozzle.

The step(s) of adding fluids to the concave cavity of the receptacle are preferably performed by injection of said fluids into said cavity without wetting any part of said cavity rim. The use of inlet and outlet nozzles as described minimises the risk of wetting the rim of the receptacle to be hermetically sealed (thereby negating the need for expensive flange-drying processing equipment). A brief drying step may be provided, as a precaution, for example by supplying an absorbent pad or hot air briefly to the flange.

A step of sterilisation may be performed after said step of sealing the receptacle has been performed.

The timing of input of fluid to the cavity and its subsequent extraction may be selected to ensure that the fluid has circulated the cavity sufficiently to provide uniform contact

with the lens. Furthermore, the tapered inlet nozzle may be directed to cause rotation of the fluid about the cavity. This circulation ensures that the lens is thoroughly and uniformly washed.

The distance between the outlet nozzle and the cavity may also be synchronised to the timing of the extraction of fluid from the cavity, such that the distance between the end of the outlet nozzle and the surface of the fluid being extracted is substantially maintained at a set distance, while the fluid is being extracted. This refinement of the fluid extraction process minimises the risk of sucking the lens onto the nozzle, which would stop the fluid from being extracted and possibly damage the lens. The lens is relatively lightweight in the fluid. By drawing the fluid from the top surface of the fluid at the same time as the fluid is being withdrawn the distance between the lens and the nozzle can be maximised, minimising the chances of sucking the lens onto the nozzle. The outlet nozzle may also be provided with a relief vent to prevent damage should the nozzle contact the lens.

According to a fourth aspect of the present invention, there is provided a blister-type package containing at least one hydrated contact lens in a concave cavity, the package having at least one of A and B, at least one of C, D and E, among the following characteristics:

A) the radius of curvature of the internal surface of the cavity is greater than 10.0 mm, or greater than 11.0 mm;

B) the ratio of the internal radius of the packed cavity to the lens back optical zone radius (BOZR) is greater than 1.1, preferably greater than 1.2 or even greater than 1.3;

C) the maximum internal height of the cavity is less than 6 mm, preferably less than 5.6 mm;

D) the vertical clearance between the lens sagittal height and the internal height of the cavity is less than 2.0 mm, or preferably less than 1.9 mm, 1.8 mm, or even 1.7 mm;

E) the ratio of cavity sagittal height to lens sagittal height is less than 1.5;

The package preferably also has at least one of the characteristics F and G as follows:

F) the diameter of the cavity opening is less than 18 mm and preferably less than 17.5 mm; and

G) the ratio of cavity opening to lens diameter is less than 1.3 and preferably less than 1.25.

The cavity is preferably circularly symmetrical. If not, the diameter referred to in F and G above is the maximum diameter.

The mass of the finished package per lens (with foil but not including further external packaging) may be less than 1.3g, preferably less than 1.2g. The empty mass of the package excluding foil, fluid and lens may be less than 1g, less than 0.8g or even less than 0.7g per lens cavity.

A preferred embodiment of the invention has all the features A to G, although embodiments may be envisaged having fewer than all.

These measures enable an 'optimum cost' (low material and shipping cost) blister pack of concave design which also offers distinctive benefits to the wearer regarding lens removal from the pack. The lens can be removed from the opened blister with a single movement and will never be turned inside-out (provided of course that it is packed consistently the correct way). While high-volume manufacturing processes can be designed such that the lens is always offered correct-way-out, current blister designs cannot guarantee that this lens orientation is maintained during transportation and lens removal.

This shallow depth of the concave cavity not only provides an overall smaller package, but also allows the user to remove the lens from the packaging by merely placing a finger across its opening, avoiding the need for the users finger nail to enter the cavity, which could contaminate the lens before it reaches the users eye and users with large finger nails can extract a lens from the cavity without having to turn the package upside-down, or perform some form of "scooping" action to coax the lens onto the

finger. The height of the cavity may be greater before sealing than it is after heat and pressure have been applied as part of the sealing process.

The package may comprise a plurality of cavities formed integrally in a single sheet. Alternatively, a plurality of individual rimmed cavities can be attached to a single sealing foil, to similar effect. Two sheets with sixteen lenses per sheet represent one month's supply for one eye, for example.

The or each cavity may be sealed with a foil, each cavity containing a lens and preservative fluid. In a preferred embodiment, a single row of (four) blisters would be separated from the sheet. Each blister is then opened by peeling, one at a time.

The volume of the cavity in its sealed condition is preferably in the range 0.8 ml to 1.0 ml, and most preferably in the range 0.85 ml to 0.87 ml. This allows for example 0.5 ml fluid, and around 1.68 mm headroom, to avoid fluid interfering with the sealing process.

Combining some of the above aspects together, a preferred embodiment of the invention comprises according to a method of manufacturing a packaged flexible contact lens comprising the steps of:

- forming and curing a dry, un-hydrated flexible contact lens in a mould;
- removing said contact lens from said mould, in accordance with the steps of the second aspect of the present invention, as set forth above;
- transferring the dry, un-hydrated contact lens from a carrying head to a packaging receptacle, in accordance with the steps of the first aspect of the present invention, as set forth above; and
- processing the contact lens in said receptacle, in accordance with the steps of the third aspect of the present invention, as set forth above,

thereby producing a packaged, sealed and hydrated contact lens.

The method may employ only a subset of the method steps listed in the fifth aspect, as set forth above.

The method steps lend themselves to being fully automated, without the need for full inspection of the process and subsequent failure rejection, which are both time consuming and costly.

The present invention further provides a method of packaging lens or a plurality of lenses in which a package has at least one cavity loaded with a dry contact lens, by a method according to any aspect of the invention as set forth above, the lens is hydrated in the cavity, the hydration fluid is exchanged for preservative fluid, and a sealing foil is fixed to the rim of each cavity so as to contain the fluid and lens. The method is preferably performed so as to ensure consistent orientation of the lens within each blister.

The invention further provides a mould, suitably flexible and adapted for use with the method of removing a dry, un-hydrated flexible contact lens from a mould, in accordance with the second aspect of the invention as set forth above. The mould may comprise a relatively flexible cavity attached to a rigid frame.

The invention further provides processing equipment specifically adapted for use performance of the steps of the method of processing a dry contact lens in a packaging receptacle, as set forth above.

The invention further provides contact lens production equipment, specifically adapted for use in the method of manufacturing a packaged flexible contact lens, as set forth above.

The invention yet further provides a package comprising a contact lens in fluid in a sealed container produced in accordance with the method of any aspect of the present invention as set forth above.

The transferral of the dry contact lens between mould and receptacle may be performed by a pick-and-place manipulator having a soft-contact head. The soft-contact head may

comprise a nozzle which has a selectable suction force that when enabled draws to the head a contact lens located in close proximity, and ensures that the contact lens is held against the head until the suction force has been disabled.

The invention yet further provides a method of supplying contact lenses to a wearer when a multi-lens package of the type set forth above is produced and dispatched by mail or courier services direct to the wearer. This service is preferably performed on the instruction of an optician. The supply of contact lenses to a resident within the territory of this patent may be from a country outside that territory.

In each aspect of the invention, the or each contact lens may be a 'daily-disposable' contact lens intended to be disposed of after being worn for no more than a single day, the package containing at least fifteen lenses, or at least thirty lenses, in one or more sheets.

BRIEF DESCRIPTION OF THE DRAWINGS

Embodiments of the invention will now be described, by way of example only, by reference to the accompanying drawings, in which:

Fig. 1a – 1d illustrates in general terms steps taken to spin-cast a dry cured contact lens;

Figs. 2a – 2d illustrate steps taken to cast-mould a dry cured contact lens, and the discarding of a flash ring prior to transfer and packaging in accordance with the present invention;

Fig. 3 is a cross sectional diagram of a mould, in which a dry cured lens has been cast for transfer and packaging in accordance with the present invention

Fig. 4 shows the improved mould of Fig. 3 being flexed to detach the dry contact lens from the mould prior to transfer;

Fig. 5 shows the dry contact lens being removed from the flexed mould including optionally a situation in which the flash ring remains on the mould;

Figs. 6a and 6b show the dry contact lens being lowered into, and rested within, a receptacle such as a hydration cap or blister pack, which has been pre-dosed with a small amount of fluid;

Fig. 7 shows the dry lens in the cavity, at the start of a hydration process;

Fig. 8 is a cross sectional diagram of the now-enlarged lens in the cavity, at the end of the hydration process;

Fig. 9 illustrates the insertion of a nozzle for removing the hydration fluid;

Fig. 10 illustrates a preferred arrangement where in two nozzles are employed to alternately apply and remove fluid from the cavity;

Fig. 11 shows the cavity and lens, after packing fluid has been added to the cavity;

Fig. 12 shows a simple device for the controlled mixing of enriching ingredient(s) for delivery to the cavity.

Fig. 13 shows the cavity, lens and packing fluid, with hermetic seal applied, thereby forming a complete contact lens package; and

Fig. 14 is a cross sectional diagram of a contact lens being removed from its packaging, with the form of the receptacle shown more to scale.

NOTE: Figs. 1 to 13 are schematic diagrams, not to scale, and with supporting apparatus, pallets etc omitted for simplicity. While one mould, lens and blister are shown in the illustrations, it is to be appreciated that in mass production many lenses will be made in parallel by apparatus having positions for fifteen, sixteen, thirty or thirty-two lenses/moulds/pack blisters at a time.

DETAILED DESCRIPTION OF THE EMBODIMENTS

Casting Contact Lenses - Introduction

The following description uses the production of cast moulded contact lenses as an example, but the skilled reader will appreciate that the principle of lens removal from the concave mould can equally be applied to lenses formed by different methods that ultimately result in cured lenses residing in concave mould pieces, for example by spin casting.

As such, Figures 1a to 1d illustrate the well-known steps taken to spin-cast a dry cured contact lens, whereby a liquid monomer 10 is put into a concave mould 20, which is spun (denoted by arrow S) to form the liquid into a cup 25. The liquid is cured during spinning, by heat or light RAD (or any other curing process), thereby forming a dry-cured lens 30 matching the profile of the inner surface of the mould.

Figures 2a to 2d illustrate the basic steps taken to cast-mould a dry cured contact lens between a pair of mating but separable mould halves 40, 44. The concave mould half 44 has an optical power curve specific to a desired lens power, while the convex half 40 has a standard curve suited to the curvature of the human eye. For the purpose the steps shown in Figures 2a - 2d, the mould halves could be of known construction. However, the concave mould half 44 is adapted for a novel method of dry lens transfer, as will be described later. There may be additional formations (not shown) for compatibility with handling equipment and or to allow the mould to stand upright on a flat surface, but these are not material to the present description. The monomer 50 is applied to the inner surface of the concave mould half 44, the mould halves are brought together (Figure 2b), and the monomer is cured, again by heat or light (not illustrated), to form a dry-cured contact lens 60 matching the profile of the inner surface of the concave mould half 44. The mould halves are separated by force, conventionally by prising apart or in this case by squeezing a specially designed mould using radial force RF (Figure 2c).

The effect of a radial 'squeezing' action RF as shown in Figure 2c is to create a gentle bending moment on the vertical ring section 62 of the outer mould, the amount of travel and hence maximum force being dictated by the small annular gap 64 between the mould pieces. A radial gap within the range of 0.5 mm to 1.0 mm is suitable, preferably 0.75mm. The resulting effect of the squeezing action is an even and controlled pinching action around the junction circle 66 of the two mould pieces, that is, at the very edge of the dry lens, resulting in the inner mould 40 being gently prised away from contact with the outer mould 44. The same squeezing action separates any flash ring 70 of surplus material that is present. Relaxing the squeezing force RF then allows the inner mould and flash ring 70 to be discarded, leaving the outer mould containing the dry lens as shown in Figure 2d. This process for separation of the moulds can be readily automated and results in damage-free lenses and damage-free flash rings. Although one would think that avoiding damage to the dry flash ring is irrelevant, it is in fact important, to ensure that small fractured pieces are not produced that would attach to the surface of the dry lens and contaminate the lens surface.

The moulds are designed so that the lens is retained in the concave mould half 44 and we shall assume for the time being that the flash ring 70 of surplus material is keyed to and removed with the convex mould half.

Whichever casting process is used, the lens 60 remains fairly well adhered to the concave mould surface, and it is a perennial challenge in the mass production of contact lenses, how to extract the lens reliably from the mould, and not to damage it in the process.

<u>Dry Lens Transfer Process</u>

Figure 3 shows a mould half 100 and cast lens 110, as may be produced by the methods of Figures 1a – 1d or 2a – 2d. The improved process of removing the dry lens and accurately positioning it in a hydration cup or, preferably, directly into a pack 'blister' is described in the following paragraphs.

Figure 4 shows the mould being flexed to detach the dry contact lens 110 from the mould. With the concave side of the lens/mould preferably facing upwards, a force 'F' is applied to the under surface of the mould 'dome' whilst the flange 115 surrounding the edge of the lens is restrained by a flange contact ring 120. Rather than a complete ring 120, it may be preferred in practice to contact only at places around the circumference (three contact lobes at 120 % spacing gives a good distribution of force). This schematic diagram shows the mould having a raised flange, but the skilled reader will appreciate that the flange could extend in the opposite direction to that shown, could have a different height, or may even be flush with the mould cavity. The effect of this flexing action is to open the 'mouth' of the 100 mould in an even and predictable manner, expanding it clear of the edge of the dry lens 60, and without distorting its delicate edge. The actual force required can be optimised by positioning the flange contact ring 120 (or lobes) at a diameter somewhat greater than the diameter of the dry lens. Tests have shown that a contact diameter of 18mm surrounding a dry lens diameter of, say, 9mm is very effective. The dry lens 110 releases contact with the mould surface without damage and remains in a central position within the now expanded moulding.

It is noted that deforming the mould in this general way has been performed to release lenses in prior processes. This is invariably done manually, however, and with the aim of tipping the lens out onto a work surface, with attendant problems as discussed in the introduction. The lens will rarely drop out of the mould under gravity alone, and knocking or prizing action is required to dislodge it completely.

Figure 5 shows the contact lens after it has released contact with the mould surface and sitting in a central position. While in this 'open' position a 'pick-and-place' vacuum (suction) probe 130 with soft tip 134 is moved into the concave cavity 136 of the lens in its mould. By application of a suction force 'V' the lens is drawn to and gently held against the tip of the probe.

The tip holding the lens is now raised clear of the opening (or the mould is lowered to achieve the same effect). The dry lens can then be moved and accurately positioned by

the pick-and-place module to another location within the production line, whilst firmly retaining the lens on the probe. Because the lens has not yet been hydrated, this operation can be done reliably and with little risk of damage. If, instead of being removed with the convex mould piece, a flash ring 118 remains mated with the concave piece (as shown in outline), then the deformation of the mould by the applied force also deforms the flash ring. The flash ring is very slightly enlarged, leaving an opening through which the dry lens can pass without damage.

Figures 6a and 6b show the dry contact lens being lowered into, and rested within, the larger cavity 140 of a hydration cup or, preferably, over a receptacle in the form of an actual package 'blister' (145). Again, flanges and other parts for standing and sealing the cavity will be provided but these are not shown for simplicity (figure 14 shows the blister in more detail). Instead of moving the pick-and-place module, the now empty mould can be removed and the cup or blister positioned under the lens, depending on the type of production machinery preferred. Releasing the suction force should allow the lens to fall into the cup or blister on its front surface, not on its delicate edge. It should be noted that the moulds can be opened and the other operations carried out in quite large 'batches'. For example the process works well for the removal and transfer of over thirty lenses simultaneously. In the preferred embodiment, a single sheet containing sixteen blisters 145 and cavities 140 would be handled in one operation.

Most hydration cups, palettes and package 'blisters', as well as the lenses are made of plastic material and, given the dry atmosphere associated with hydrogel contact lens manufacture, the surfaces are often heavily charged with static electricity, rendering release and positioning of a light dry lens 110 very difficult. In a batch of thirty lenses at least some will remain adhering to the suction probe, possibly on the side thereof, or scattered across the surface of the blister sheet instead of in their respective receptacles. Dry lens transfer has not been adopted widely in the art for these reasons. Whilst process steps can be taken to try to control such static electricity, these can be a troublesome and involve relatively costly processes. Performance may vary according to the weather, making quality control a hopeless task.

In the improved process, the cavity 140 is pre-dosed with a very small spot 150 of saline or water, having a volume of less than 0.07 ml. Upon contact with the lens 110, this small droplet immediately retains the dry lens, holding it in a predictable, generally central position in the cup or blister. The fluid is preferably sterilised pure water. Additives that would reduce surface tension might reduce the capture effect. If normal saline solution were used, salt crystals might form and block the tiny orifices and valves required to dispense such small doses. Subsequent movement of the cup or blister is easily conducted because there is no risk of the otherwise dry lens moving in the vessel. Also, the lens is always retained in the same orientation. This combination of precision of placement, avoidance of movement and guaranteed orientation means that the cup or pack blister into which the lens is being placed can be restricted to being little larger than the actual hydrated lens. Minimum pack size is a distinct advantage especially for low cost disposable contact lens manufacture, as described in the Applicant's co-pending international patent application WO 03/039969A [Agent's ref 63965WO].

The ideal quantity of fluid in the pre-dose spot to maximise consistency will depend upon the composition of the fluid, and also on the exact shape and materials of the carrying head, receptacle and lens, and should be determined by experiment. Experiments show that the exact dose is not critical. In a prototype system the volume over a palette of 32 cavities averages 0.012 ml, with individual doses ranging from 0.001 ml to 0.053 ml. Placement error rates better than 1 in 1000 or even 1 in 2000 lenses are achieved.

Figure 7 is a cross sectional diagram of the dry lens 110 in the cavity 140, at the start of the hydration process. It is important to hydrate and wash the dry lens, in particular, to 'extract' any un polymerised materials in the dry lens matrix. Therefore, the cup or 'blister' is dosed with saline or water 210 sufficient to fully hydrate the lens. Hydration takes approximately 15 to 30 minutes, during which the lens grows to its final size.

Figure 8 shows the now-enlarged lens 110 in the cavity 145, at the end of the hydration process. The lens has grown by hydration to substantially match the internal radius of the cavity. The lens is not ready for packaging, however, because uncured monomer and other chemicals will have leached into the liquid, and need to be washed away.

Figure 9 shows a second suction probe 130, again with a soft tip, being lowered into the hydration liquid 210 and the liquid being sucked out via this tube. A second fill is then made immediately, followed by a further evacuation of the liquid. This simple process is repeated until all extractables are washed from the cup or blister by a process of repeated dilution.

Figure 10 shows the preferred embodiment whereby repeated filling and removal of the subsequently contaminated washing liquid takes place using two co-located soft tipped tubes, a first tube 230 for input, and a second tube 240 for extraction. The number of 'flushes' required is dependent on the effectiveness of the original polymerisation process and the relative purity of the monomer. Typically four or five flushes should suffice. The amount of fluid used is much less than in bulk hydration described above and, more importantly, the flange 245 of the blister 145 is never wetted. This is important, because even very small amounts of moisture on the flange can prevent sealing. The skilled reader will appreciate that instead of a distinct time delay between the input of fluid into the cavity, and its subsequent removal, the input and removal could be occurring simultaneously, or as a series of out of phase pulses.

The first, inlet tube 230 is shaped and may be located well to one side of the cavity axis (more than shown). This helps to direct the stream of fluid in such a manner as to maximise the coverage of the fluid under and over the lens as the fluid is streaming into the cavity 140. Doing so ensures even washing of both surfaces of the lens 110.

The second, outlet tube 240 is located as centrally as possible. This is to maximise the amount of contaminated fluid that can be removed from the cavity. The lens is relatively lightweight in the fluid. In order to minimise the risk of the lens being sucked onto the extraction nozzle while extracting the fluid, the distance between the nozzle

and the cavity can also be synchronised to the timing of the extraction of fluid from the cavity, such that the distance between the end of the outlet nozzle and the surface of the fluid being extracted is kept as close as possible to a set distance. The lens being sucked onto the nozzle would stop the fluid from being extracted and possibly damage the lens. By drawing the fluid from the top surface of the fluid at the same time as the fluid is being withdrawn the distance between the lens and the nozzle can be maximised, minimising the chances of sucking the lens onto the nozzle. Small apertures in the sides of the probe tip can also be provided to prevent the full force of the vacuum capturing the soft lens, as a precaution.

Figure 11 shows the cavity and lens, after packing fluid has been added. This occurs after the last 'flush' has been completed, the cup or blister 145 being dosed with the fluid to around 50% of the cavity volume.

For soft lenses intended for single-use (for example, daily disposable lenses) it is possible to improve the comfort, wetability and movement of the lens on the eye by adding a 'comfort' ingredient at this stage to the packing solution (for example, a surfactant). There can be other benefits by, for example, the addition of dexpanthenol. Dexpanthenol has the effect of reducing the sensation of eye dryness and of helping to repair any damage of the epithelium which may be present at the time the lens is inserted or by the process of inserting the lens or by some action during wearing of the lens (for example as can be caused by rubbing of the eye). Enriching the final packing solution can be carried out by the addition of one or more of these materials to one or more of the process steps hereinbefore described, with reference to Figures 7 to 11. The optimum step to carry out this 'enriching' process at the final packing solution filling stage. However, the same effect can be achieved by enriching the solutions used in prior washing stages, as there will be a carry over of the enriched solution in the matrix of the lens and/or in the wet coating of the blister pack.

Figure 12 shows schematically a simple device 262 for the controlled mixing (by way of mixer valve 264) of the chosen enriching ingredient(s) 266 with, for example, saline packing fluid 260, prior to the mixture being delivered to the lens/blister. The entire

pick-and-place apparatus can be operated by pneumatic power and actuators of conventional types. Peristaltic pumps or syringes driven by stepper motors for example can deliver precisely metered quantities of fluid under computer control.

Figure 13 shows the blister 145, lens 110 and packing fluid 260, with hermetic seal 270 applied, thereby forming a complete contact lens package. More detail can be seen in WO 03/039969A mentioned above. A lid is generally secured by the heat-sealing of metal/plastic film/foil to the rim of the blister, although the skilled reader will appreciate that other techniques are available for achieving the same function, such as by use of adhesives, or by using alternative forms of radiation to effect the seal.

The complete lens and pack assembly is then sterilised, generally by autoclaving.

Shallow Blister

Careful control of the lens and fluid means that the lens can be reliably placed hydrated and washed in a very small cavity 140. WO 03/039969A mentioned above explains how a shallow blister, whose inner radius of curvature may closely match that of the hydrated lens, reduces pack weight, volume and cost, and also facilitates removal of the lens by the user. The dry transfer techniques described above are suited to the filling of such shallow blisters, and even allow an even shallower blister to be used than the one proposed in WO 03/039969A itself.

Figure 14 shows one blister of a novel blister pack after opening. Use of an even shallower blister 300 allows a contact lens 310 to be removed from its packaging by a finger 320 without the risk of the fingernail 330 touching the packaging fluid (not shown), possibly contaminating the fluid and risking infecting the eye. It has been observed that a conventional, deeper package would require the fingernail to enter into the cavity, which may prevent the lens being removed by conventional means, requiring instead some other way, such as turning the package on its side, or upside down, in order to coax the lens out. Obviously, these latter methods risk loss of or damage to the lens, and are considerably less convenient to the user. Depending on the

length of the fingernail, even the relatively shallow packages of WO 03/039969A or WO 99/27813A may present difficulty to certain users. WO'813 has a more complex shape to improve access.

In the preferred embodiment, the blister filled mass may be around 1.1g per lens, being just 87% of the blister shown in WO 03/03996A. The empty blister sheet in the example weighs only 0.64g per lens, certainly less than the pack of WO'813 which weighs around 1.7g empty for a single lens, including foil. In terms of dimensions:

- The blister internal height (after sealing) may be less than 6 mm, for example 5.9 mm and preferably less than 5.6 mm.
- At the same time, the internal radius of curvature may be greater than that of the lens, rather than closely matched. For example, for a typical lens back optical zone radius (BOZR) of 8.6 mm, the cavity 140 may have a radius of curvature greater than 10 mm, or greater than 11 mm, for example 11.2 mm. The ratio of blister dish radius to lens BOZR may be greater than 1.1, 1.2 or even 1.3 (11.2/8.6 = 1.31 in the example).
- The vertical clearance within the sealed cavity to the edge of the lens may be less than 2 mm, and even less than 1.9, 1.8 or 1.7. In the preferred embodiment, for a lens with maximum sagittal height 3.82 mm, the blister cavity internal height of 5.5 mm gives a blister/lens height ratio of 1.44, and clearance 1.68 mm. This compares with clearance over 2 mm in known packs and ratios over 1.5.
- Lens diameters may be around 14 mm, for example 14.3 mm. The blister opening diameter may be around 17 mm, for example 17.3 mm. The ratio of blister opening to lens diameter may thus be less than 1.3 or even less than 1.25. (17.3/14.3 = 1.21). This compares with over 1.4 and nearer 1.5 for most known packages.
- The pack is therefore smaller in footprint and height, as well as being easier to use than known packs.

Summary

The whole process is very repeatable and results in low-cost, damage-free, lenses. It requires little capital expenditure even to operate at very high production levels. The lenses are dry at the time when they are moved over and into the blister dishes, so that fluid does not drip onto the flanges of the blisters. The amount of water used is a fraction of bulk hydration methods used in contact lens manufacture. By ensuring that mould-pack is presented to the pack sealing machines with no trace of moisture on the flange area (sealing surface), there is no need for expensive flange-drying processing to remove any moisture on the sealing surface that could result in ineffective pack closure if it was not removed.

The expansion of the mould to allow clearance for lifting the lens free of the mould is carried out within the 'elastic-limit' of the mould material. The mould can be used for repeated cast moulding operations because the mould 'relaxes' back to its original form without damage, providing the potential for significant cost savings.

It has been found that the above process is also effective even if any flash ring created by the moulding process remains attached to the concave mould. The expansion process previously described also has the effect of expanding the flash ring diameter, thereby allowing the lens to be lifted from the cavity through the expanded flash ring, leaving the flash ring in the mould, to be flushed away if the cavity is prepared for re-use.

The process allows a very shallow blister dish to be loaded reliably with lens and fluid, and also to be used as the hydration and washing vessel, all without total immersion of the pack in fluid, wetting only the blister cavities themselves. This reduces cost in the procedure, and in stocking and transporting the lenses, while most importantly improving usability for the lens wearer.

The skilled person will further appreciate that the exact form of components and methods used can vary from the ones described herein without departing from the spirit and scope of invention.